

# **NAVAL MEDICAL LOGISTICS COMMAND**

## **QUALITY POLICY MANUAL**

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## 1.0 INTRODUCTION

The Naval Medical Logistics Command (NMLC) is dedicated to fulfilling the Medical Logistics needs of the Navy and Marine Corps Operating Forces and Shore Establishments. We provide our customers with equipment, supplies, healthcare services, consultative and management services necessary to perform their mission and maximize medical readiness during peace and war. The organization is built around the concepts of teamwork, flexibility, and streamlining to ensure that work processes are both efficient and effective with the intent of establishing a dynamic organization that provides an environment conducive to institutionalizing the concepts of Total Quality Leadership (TQL). NMLC sees the tenets of TQL as the means by which to achieve ISO 9002 compliance and registration. TQL invokes the principles of customer focus, total involvement, and measurement and provides a systematic approach to continuously improve our work processes, the personal and professional development of our staff and the work environment, and achieve our organizational goals and objectives.

### Naval Medical Logistics Command Strategic Goals and Objectives

**Goal 1:** We will maximize the potential of each staff member.

**Objective 1.1:** Promote and support professional growth and development opportunities.

**Objective 1.2:** Continually promote reward and recognition programs.

**Objective 1.3:** Establish an environment that encourages and supports educational opportunities.

**Goal 2:** We will provide superior service to our customers.

**Objective 2.1:** Market medical logistics services and capabilities to our customers.

**Objective 2.2:** Optimize customer service awareness skills for staff members.

**Goal 3:** We will provide the foundation for the three pillars of force health protection through integrated logistics solutions.

**Objective 3.1:** Develop processes that will lead to the standardization of medical and dental equipment and consumable items for Medical and Dental Treatment Facilities (MTFs/DTFs) and deployable platforms.

**Objective 3.2:** Develop and manage an Integrated Logistics Support (ILS) acquisition program for medical and dental equipment.

**Objective 3.3:** Develop methodologies to align medical materiel requirements determinations with DoD structures to effectively manage medical and dental assemblages.

**Objective 3.4:** Obtain feedback from lessons learned and After Action Reviews of pertinent operational activities (exercises, conferences, war games, and working groups.)

**Goal 4:** We will enhance medical logistics capabilities through technology integration and business practice reengineering initiatives.

**Objective 4.1:** Support and educate our customers on integrating new logistics and information management technologies.

**Objective 4.2:** Implement, integrate, and sustain emerging technologies and business practices.

**Goal 5:** We will provide the most innovative and efficient contracted healthcare delivery and other service systems to customers, buying best value medical, dental and other goods and services that meet or exceed our customers' requirements.

**Objective 5.1:** We will satisfy our customers with efficient, cost and delivery effective, comprehensive support in every phase of the acquisition cycle.

**Objective 5.2:** We will team with Navy and DoD technical professionals, customers and vendors to deliver procurement support that meets or exceeds each customer's needs; right product, right price, right time, and the right place.

**Objective 5.3:** We will consult, analyze, and develop high quality, effective alternative service systems.

The purpose of this quality manual is to define the methods and procedures used by NMLC to ensure an effective and economical system of maintaining quality medical logistics support activities.

The methods and procedures are in conformance with "ISO 9002: 1994 Quality Systems Model for Production, Installation and Servicing" and define working agreements between departments for effective control of the command. Procedures provide for the prevention and detection of discrepancies, establishment of record keeping and closed loop corrective action. All unclassified and non-procurement sensitive records, certifications, documents, processing, etc. are available for customer and outside agency auditing.

This manual defines the quality system and our procedures (Management Operating Procedures - MOPs) and work instructions (Standard Operating Procedures - SOPs) provide additional detail. Procedures address the "what, when and where" for each specific ISO requirement and include responsibilities, objectives, and activities for each applicable function in the organization. Where deemed necessary, SOPs provide step-by-step details on how to perform specific tasks and include criteria for determining compliance.

It is intended that NMLC's quality system, as defined in this Quality Policy Manual, be applied to all services within the scope of registration as defined by the ISO MAP (master list of documents) and customers included therein. On occasion, the quality system may need to be tailored for specific contractual situations. In such cases, any variations shall be in compliance with the appropriate ISO standard.

## 2.0 SCOPE OF APPLICATION

### Scope

This Quality Policy Manual specifies the procedures used by NMLC to control the processes that determine the acceptability of the procurement, logistics, and healthcare services provided to our customers.

The processes delineated in this manual are aimed primarily at the prevention and early detection of any non-conformity and to eliminate root causes of non-conformities and prevention of any recurrence.

## 3.0 REFERENCES

- ANSI/ISO/ASQC Q9002-1994 American National Standard; Quality Systems - Model for Quality Assurance in Production, Installation, and Servicing.

## 4.0 QUALITY SYSTEM REQUIREMENTS

### 4.1 MANAGEMENT RESPONSIBILITY

The Commanding Officer and Executive Steering Committee (ESC) function as the senior management team for NMLC. The ESC plays a key role in TQL implementation and ISO 9002 compliance. As the controllers of the resources of the organization, they are in a position to directly impact the success of the organization. This team functions collectively to guide and direct the efforts and resources of the organization, under the direction of the Commanding Officer. **Their commitment must be evident for the entire staff to support the goals and objectives of the organization.**

**The ESC membership consists of the Commanding Officer, Executive Officer, Directors, Command Counsel, Command Senior Chief, Management Representative, TQL Coordinator, and Command Internal Audit Officer.** They are responsible for NMLC's quality system. They have documented the Command's "Quality Policy" and objectives that define the Command's commitment to quality. As a part of its orientation and overall training program, NMLC ensures that all employees understand the Quality Policy and that it is implemented and maintained at all levels of the organization. NMLC's Quality Policy is located on **page 04** of this manual.

### Resources

NMLC has identified the resource requirements and provides adequate resources (in the form of trained personnel, equipment, and facilities) for management, performance of work, and verification activities including internal audits.

## Authority

The responsibility, authority and interrelation of personnel who manage, perform and verify work affecting quality are defined within the quality system's MOPs, SOPs, Appointments Letters, Position Descriptions, and NMLC's Command Organizational Manual.

**Organizational Chart and Functional Area Descriptions are located in Appendix A** of this manual. Within each functional area, of our scope of registration, NMLC employees have the responsibility and authority to:

- a) Initiate corrective action to prevent the occurrence of product or service non-conformity;
- b) Identify and record any product or service quality problems;
- c) Initiate, recommend or provide solutions through designated channels;
- d) Verify the implementation of solutions and the effectiveness of those solutions;
- e) Control further processing, delivery or installation of non-conforming product or services until the deficiency or unsatisfactory condition has been corrected.

## Quality Policy

NMLC has established a "Quality Policy" to ensure our procurement and logistics services satisfy our customers requirements. **The objectives outlined above in section 1.0**

**Introduction document not only our Strategic Objectives but also our Objectives for achieving, sustaining, and improving quality.** NMLC is committed to its quality system and all employees participate in the system.

*We are committed to setting the standard for professional excellence by exceeding our customer's needs with quality medical logistics support.*

*We will identify and obtain cost effective and technologically sound medical materiel and health care services to support the continuum of care that maximizes the readiness of the Naval Service worldwide*

*We will continuously strive to improve our processes through the use of a self-sustaining total quality system.*

---

*Commanding Officer*

## Management Representative and Other Quality Management System Key Personnel

The **Management Representative** is responsible for, and is authorized to monitor, review and initiate corrective actions to ensure that those quality activities in each functional area, within the scope of our registration, are carried out in full compliance with the documented quality system. Ultimately, the Commanding Officer is responsible for the timely and effective execution of approved corrective action plans.

The Commanding Officer of NMLC has appointed a Management Representative. The Management Representative, irrespective of other responsibilities, has the authority of ensuring that the requirements of the ISO 9002 standard are established, implemented and maintained. The Management Representative reports on the performance of the quality system to the Commanding Officer and the ESC.

In addition to the Management Representative, the Commanding Officer has appointed a **Command Internal Audit Officer, Corrective Action Coordinator, Quality Document Control Coordinator, and a Quality Records Coordinator**. The Executive Officer, by position, is the Command's Corrective Action Administrator. The duties, responsibilities, and qualifications for each of these positions are described in **Appendix B, Command Quality Management System Key Personnel Duties and Qualifications**. As of July 1<sup>st</sup>, 1999 all incumbents meet the minimum qualifications for their positions. All subsequent appointees must meet the criteria established in Appendix B unless specifically waived by the Commanding Officer.

## Management Review

The Commanding Officer conducts reviews of the quality system at least quarterly and more often as required, with NMLC's Management Representative and the ESC. They systematically evaluate the quality system to ensure its continuing suitability and effectiveness in satisfying the requirements of ISO 9002, meeting the needs of our customers, and continuously improving our processes.

Management reviews, as appropriate, include:

- (a) Review of outstanding agenda items from previous meetings;
- (b) Assessment of the results of internal and external quality audits;
- (c) Assessment of customer feedback.
- (d) Review of product and service performance trends and customer complaints to determine the adequacy of the quality system based on field data and performance metrics;

- (e) Status of Preventive and Corrective Actions and the effectiveness of the corrective actions taken to eliminate the root causes of the discrepancies. Special attention is given to “High Risk” and long standing open Corrective and Preventive Actions (greater than 6 months).
- (f) The overall effectiveness of the quality management system in achieving the objectives of NMLC’s Quality Policy relative to the command’s objectives;
- (g) Considerations for updating the quality system in relation to changes brought about by new technologies, quality concepts, market strategies and environmental conditions.

The ESC prepares a written record of management reviews as part of the ESC minutes and includes recommendations and requirements for corrective actions to be taken by responsible departments. Action items resulting from these meetings will be assigned specific due dates for subsequent review by the management team.

## 4.2 QUALITY SYSTEM

### General

As a means of ensuring that the services, supplies, and equipment conform to specified requirements, NMLC has established and maintains a documented quality system. This quality system consists of a Quality Manual that describes the manner in which the quality system is implemented to ensure that products and services conform to specified requirements. The Quality Manual includes and/or references the quality system procedures and outlines the structure of the quality system. The quality system defines the organizational structure, responsibilities and procedures that further define the process and resources for implementing and maintaining quality management to accomplish NMLC’s quality policies and objectives.

### Quality System Procedures

The operating procedures of each functional area that affect the quality of the services and supplies are documented, reviewed, released and maintained as described in **Section 4.5**. The managers/process owners of each functional area have the responsibility and authority to direct the documenting of the methods required in the performance of their departmental functions and to ensure their implementation and execution to achieve the established quality objectives. All employees at NMLC are empowered to initiate, develop and recommend changes to processes or procedures documenting those processes. New procedures and changes to existing procedures must be reviewed and approved by the issuing authority or process owner.

### Hierarchy of Quality System Documents:

- **Quality Manual:** First-level document that provides a general overview of the quality system and defines the Quality Policy. The Quality Manual is divided into sections corresponding to each of the elements of the ISO 9002 standard.

- **Quality System Map and Management Operating Procedures or MOPs:** Second-level documents or **procedures** that describe in detail how the policies of the Quality Manual are implemented; define who is responsible for the activities; discuss interrelationships between different departments within the command; list the deliverables and quality records of the defined process and describe the closed-loop systems which ensure that quality measurements are reported to the individuals responsible for improving the quality system.
- **Standard Operating Procedures or SOPs:** Third-level documents or **work instructions** that provide step-by-step direction for executing activities. SOPs may or may not be necessary and will therefore be used at the discretion of the functional area managers/process owners.
- **Quality Records:** Fourth-level documents that contain the data, charts, checklists or other records which demonstrate conformance to specified requirements and the effective operation of the quality system.

### Quality Planning

NMLC defines and documents how the requirements for quality are met through TQL implementation, strategic/annual planning, and the Command QPM, MOPs and SOPs. As part of TQL implementation, the ESC charts Quality Management Boards (QMB) which are working groups charged with the oversight and quality planning of a particular product line (e.g. Acquisition Planning Group for Services or APGS). QMBs have the authority to charter and sponsor functional and cross-functional Process Action Teams (PATs) to address vertical and horizontal work processes respectively. Initiatives undertaken by QMBs and PATs are reported to the ESC and in some cases added to the strategic/annual planning process.

At the beginning of each fiscal year, directors and process owners document their annual quality plans using the **NMLC Annual Planning Table 4.2M1.F1**. These documents are completed for key programs, projects, or processes and links the activity to one or more of NMLC's strategic goals, objectives, and strategies. The plans specifically identify the critical tasks, resources, actions, milestones, and metrics associated with each key program, project, or process. Also, on a quarterly basis or more often as required, directors and process owners brief the ESC on the status of their key programs, projects, or processes using the **NMLC Program Quarterly Briefing Format 4.2.M1.F2**. This format allows directors and process owners to focus on areas of concern and gives the ESC an opportunity to ask questions, analyze data, and direct resources as required.

NMLC will give appropriate consideration to the following activities in meeting customer requirements when deemed appropriate by management:

- a) The preparation of quality assurance requirements for supplies, equipment, and services as required,
- b) Identification, development, and/or procurement of any controls, processes, equipment, fixtures, resources and skills that may be necessary to achieve the required quality;
- c) The identification of suitable review and verification at appropriate stages in our work processes;
- d) Clarifying standards of acceptability for all features and requirements, including those which may be subjective;
- e) Identifying and preparing of quality records.

### 4.3 CONTRACT REVIEW

#### General

NMLC's charter is to provide Services, Supplies, and Equipment through acquisition to fulfill the needs of the Operating Forces and Shore Establishments. The activities that define how NMLC will review and document our customers' requirements to ensure we understand their needs and can satisfy their requirements and expectations are incorporated into the Process Control procedures, as appropriate.

### 4.4 DESIGN CONTROL

This element does not apply within the scope of the NMLC ISO 9002 quality system registration.

### 4.5 DOCUMENT AND DATA CONTROL

#### General

NMLC has established and maintains documented procedures to control the review, approval, issuance and use of all documents and data affecting the quality and the requirements of ISO 9002. Reference **Quality System Document Control Procedure 4.5.P1 & External Document Control Procedure 4.5.P2**. Records generated during the control of documentation and data are maintained. All controlled documents are reviewed and approved for adequacy by authorized personnel, prior to issue. The document control system ensures that:

- a) Current revisions of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
- b) Invalid and/or obsolete documents are promptly removed from all points of issue, use, or are otherwise assured against unintended use;
- c) Any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

Documents included within the document control system are:

- Quality Policy Manual
- In-scope MOPs, SOPs, and related forms
- Externally Originated/Controlled Documents and Work Instructions

## **Document and Data Changes**

Changes to controlled documents and data are reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise. The designated functions/organizations have access to pertinent background information on which they base their review and approval.

## **4.6 PURCHASING**

### **General**

NMLC has established procedures to ensure that purchased product or service conforms to specified requirements. Records generated during the purchasing process are maintained. NMLC provides supplies and services to our customers through contracts with vendors and individuals who are referred to as government contractors. These contractors are selected on the basis of their ability to meet our customer's requirements, including the quality system and any specific quality assurance requirements.

NMLC defines the type and extent of control exercised over contractors, based on the supplies or service type, the impact on the quality of the final supplies or services, and where applicable, on the quality audit reports and/or records of previously demonstrated capability and quality performance. NMLC considers proposals from all responsible sources in accordance with applicable statutes and regulations; however, past performance is always used as a method to select the best source. Records of contractor performance are maintained.

### **Purchasing Data**

NMLC maintains documented procedures to control the services and supplies acquisition process, as appropriate to its services and quality system. Reference **NMLC Acquisition Management Directorate, Self-Assessment/Quality Assurance Plan 4.6.M1** clearly requires purchasing documents for products and services to be acquired and are reviewed for accuracy prior to release.

NMLC procurements can be categorized as follows:

- Procurement of medical and dental materiel for the outfitting of medical and dental spaces of new and existing ships and submarines.
- Procurement of equipment and consumables for improved readiness and new programs.

- Procurement of medical and dental equipment for Navy Medical and Dental Treatment Facilities
- Procurement of medical and dental materiel for the United States Marine Corps.
- Procurement of healthcare services: physicians, dentists, nurses, physical therapists, social workers, childcare, etc.

### **NMLC Verification at Contractor's Premises**

NMLC rarely engages in this activity. However, when the need to verify purchased product at the contractor's facility is determined, specific verification arrangements and the method of product release will be addressed in the contract requirements. NMLC verification does not absolve the contractor of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by NMLC.

### **Customer Verification of Contracted Product**

This requirement is generally not applicable to NMLC; however, where specified in the contract, a NMLC customer or customer's representative is afforded the right to verify that the contracted supplies or services conform to specified requirements. Such verification shall not be used by NMLC as evidence of effective control of quality by the contractor.

## **4.7 CONTROL OF CUSTOMER-SUPPLIED PRODUCT**

This requirement is not applicable to NMLC.

## **4.8 PRODUCT IDENTIFICATION AND TRACEABILITY**

NMLC defines Product Identification and Traceability as the capability to track an individual customer requirement throughout the entire acquisition process. This system is embedded and described within the Purchasing and applicable Process Control procedures. The identity of our services is maintained by various means. Typical methods of identification and traceability include: Equipment Nomenclature, Purchase Request Number, Document Number, Contract Number, Lot Number, Transportation Control Number (TCN), and National Stock Number (NSN).

## **4.9 PROCESS CONTROL**

### **General**

NMLC defines and describes primary processes and outcomes to ensure we are consistently providing excellent service to our customers through our ability to control those processes. Adherence to these procedures ensures that our acquisition processes are performed under controlled conditions.

Given the nature of NMLC's business processes, many of the requirements of this element do **not apply directly** to NMLC; however, those deemed applicable may be imposed on contractors, as necessary. Those that do apply directly to NMLC are embedded within the

applicable level II and III procedures. NMLC will give appropriate consideration to the following activities in meeting customer requirements when deemed appropriate by management:

- a) Documented MOPs and SOPs that define the methods of effectively discharging our acquisition and logistics services to our customers, where the absence of such documentation could adversely affect quality. This documentation provides the “what and when” information of a given process and details instructions on “how to” perform the specific job functions.
- b) The use of suitable equipment and a suitable work environment;
- c) Compliance with reference standards/codes, quality plans and documented procedures;
- d) Monitoring and controlling process parameters and product characteristics;
- e) Approval of processes and equipment, when appropriate;
- f) Criteria for workmanship described in written standards, representative samples or illustrations;
- g) Suitable maintenance of equipment to ensure continuing process capability.

NMLC does not have any special processes located onsite.

## 4.10 INSPECTION AND TESTING

### General

NMLC does not engage in Inspection and Testing outside of the acquisition and logistics processes. Within the acquisition and logistics processes are contract and requirement document review and approval procedures. Receiving and in-process inspection activities are embedded within our processes and describe how we will inspect our own work, in various stages, recording the results to ensure our work conforms to the requirements of our established procedures. NMLC acquisition processes, where applicable, define the requirements contractors must use to verify that supplies and equipment are verified against NMLC-specified requirements, prior to dispatch to our customers. The supplies, services, and equipment delivered, as a result of our contracts, are inspected in accordance with contract requirements.

## 4.11 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

### General

This activity is not applicable to NMLC activities for the reasons stated above in Section 4.10 Inspection & Testing, under the heading “General”.

## 4.12 INSPECTION AND TEST STATUS

### General

Embedded within NMLC’s acquisition and logistics processes are work in-process inspection and testing activities which describe how we will inspect and test our own work, in various stages, and record the results of these inspections and tests to ensure our work conforms to the requirements of our established procedures. Process owners maintain and control inspection and test results as quality records as required by their documented procedures. The supplies, services, and equipment delivered, as a result of our contracts, are inspected and tested in accordance with contract requirements and documented in the contract file.

## 4.13 CONTROL OF NONCONFORMING PRODUCT

### General

Nonconformances are instances where the service we delivered did not meet the customer’s expectations. **NMLC defines a customer as “anyone who comes to NMLC with an expectation of assistance.” And a customer complaint is defined as “when NMLC becomes aware that NMLC has not met a customer’s expectation.”** NMLC ensures that supplies, equipment and services that do not conform to specified requirements are identified, documented, evaluated, segregated (when and where practical) and that we notify the affected stakeholders. Where appropriate, these requirements are also embedded within our acquisition processes in order to prevent nonconforming supplies or equipment from unintended use or installation at our customer locations. NMLC may also employ the use of customer surveys in order to assess whether or not NMLC healthcare delivery services have met our customer’s expectations and the subcontract requirements. Opportunities for improvement may be processed through our Corrective and Preventive Action systems.

## 4.14 CORRECTIVE AND PREVENTIVE ACTION

### General

NMLC has established and maintains documented procedures for managing corrective and preventive actions taken in areas that may affect the quality of supplies, equipment or healthcare services delivered to our customers. Reference the **Corrective and Preventive Action Procedure 4.14.P1**.

Corrective and preventive actions are taken to eliminate the causes of actual or potential non-conformities in the degree appropriate to the magnitude of the problems and commensurate with the risks involved. NMLC implements and records any changes to documented

procedures and work instructions which result from any corrective or preventive actions taken. Records are maintained to document the investigation and resolution of corrective actions.

### **Corrective Action**

Documented procedures provide for:

- a) Effective handling of customer complaints and reports of supplies, equipment or healthcare service non-conformity and to detect and eliminate potential causes of non-conforming product or service;
- b) Investigating the cause of non-conformities related to supplies, equipment or healthcare services, process or the quality system, and recording the results of the investigation;
- c) Determining the corrective action needed to eliminate the cause of non-conformities;
- d) Applying controls to ensure that corrective actions are taken and that they are effective.

### **Preventive Action**

NMLC documented procedures include:

- a) The use of appropriate information sources such as processes and work operations which affect product quality, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of non-conformities;
- b) Determining the steps necessary to deal with problems requiring preventive action;
- c) Initiating preventive action and application of the controls to ensure its effectiveness;
- d) Ensuring that relevant information on actions taken is submitted for management review.

Any customer may initiate a Corrective Action Request (CAR). Customers may logon to the NMLC Web Page at <http://www-nmlc.med.navy.mil>, click on “**CONTACT US,**” select **Suggestion, Complaint, or Opportunity for Improvement** at the subject line, fill in the requested information, and describe the non-conformance under Comments. The CAR will automatically be forwarded to the Corrective Action Administrator (CAA), Corrective Action Coordinator (CAC), and Management Representative. NMLC employees should document their CAR using the **Corrective and Preventive Action Procedure 4.14.P1**.

## **4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY**

### **General**

NMLC does not store, package, or deliver any of the supplies or equipment procured through the acquisition process. NMLC Acquisition activities, where applicable, define the requirements that contractors must use to ensure that supplies and equipment are stored, packaged, preserved (as required) and delivered in accordance with specified requirements.

## 4.16 CONTROL OF QUALITY RECORDS

NMLC has established and maintains documented procedures describing the identification, collection, indexing, accessing, filing, storage, maintenance and disposition of quality records that may exist in either hard copy or soft copy. Reference the **Quality Records Procedure 4.16.P1**.

Quality records are maintained by the process owners to demonstrate the achievement of conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from contractors are also an element of this data.

NMLC quality records are stored and maintained in a suitable environment to minimize deterioration, damage and to prevent loss. The records are maintained in a manner that makes them readily retrievable. NMLC quality records are legible and identifiable to the supplies, equipment and healthcare services provided. Each Level II and III document identifies the applicable quality records and includes the record name or title, storage location, indexing method, retention period, and method of disposition. When required contractually, quality records are made available for evaluation by the customer or the customer's representative for an agreed-upon period of time.

## 4.17 INTERNAL QUALITY AUDITS

NMLC has established a documented, comprehensive system for planning and executing internal quality audits to ensure quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. Reference the **Internal Quality Audits Procedure 4.17.P1**.

Audits are scheduled on the basis of the status and importance of the activity and are carried out by personnel independent of those having direct responsibility for the activity being audited.

Results of internal quality audits are documented and brought to the attention of the management personnel having responsibility for the area audited. The responsible managers take timely corrective action on the deficiencies found during the audit. Follow-up audits are then performed to verify and record the implementation and effectiveness of the corrective actions taken. NMLC maintains records of all internal audits.

## 4.18 TRAINING

NMLC has established and maintains a documented system for identifying training needs and providing training for all personnel performing activities that affect quality. NMLC employs Civilian, Military and Contract personnel. Reference the **NMLC Civilian and Military Training Procedure 4.18.P1**, **NMLC Civilian and Military Mandatory Training Procedure 4.18.P4**, and **NMLC Command Orientation Process 4.18.P5**. Personnel are qualified on the basis of appropriate education, training and experience. Officer and Enlisted Billet Codes,

Civilian Position Descriptions (PDs), and Command Appointment Letters are the primary methods used in identifying the education, training and experience required by NMLC personnel.

**All personnel assigned to, or employed at NMLC meet the minimum qualifications for their billet or position upon reporting aboard.** Military members are selected and assigned by the Navy Military Personnel Command (NMPC) located in Millington, TN, using the education, training, and grade criteria established for each billet. Civilians are screened by the Human Resources Service Center (HRSC) Washington, DC, to ensure they meet the minimum qualifications per the applicable PD prior to their selection. Contractor personnel must meet the minimum qualifications documented in their particular Statement of Work (SOW) as part of the contract requirement.

Additional training needs for military and civilian personnel, as required, are identified during the annual performance evaluation process and are documented on Individual Development Plans (IDPs). Contract personnel performance is periodically evaluated by the Contracting Officer Representative (COR) and assessed to determine if contract personnel meet contract requirements.

Directors are responsible for identifying the specific training needs of their personnel and coordinating the appropriate training with the Military or the Civilian Training Representative. NMLC maintains documented records of personnel training requirements, training schedules (if applicable) and training completed.

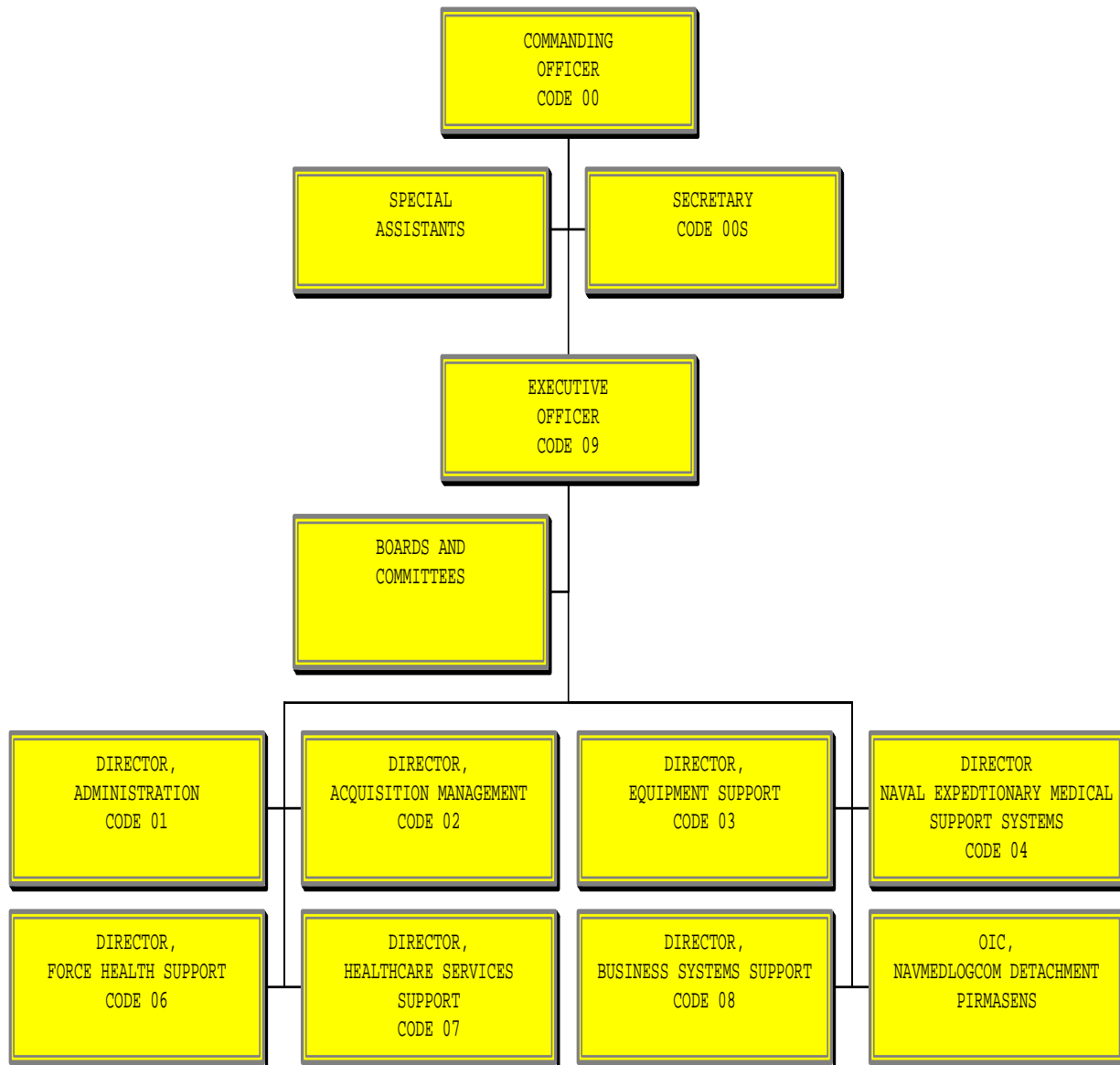
#### **4.19 SERVICING**

This element is not applicable to NMLC.

#### **4.20 STATISTICAL TECHNIQUES**

NMLC has not identified the requirement for Statistical Techniques. However, if and when a need for them is determined, NMLC will identify the data elements and collection techniques necessary to control their application with applicable processes and procedures.

## Appendix A - Command Organizational Chart and Functional Area Descriptions



### COMMANDING OFFICER (Code 00)

Serves as the Assistant Chief for Logistics, BUMED, Program Executive Officer, Fleet Hospital Program and Commanding Officer. Coordinates, administers and provides oversight for all activities within the claimancy and the command. The Assistant Chief for Logistics coordinates health care services contracting policy and procedures within the BUMED claimancy; to direct, manage, and control logistical and materiel systems under BUMED during peacetime and contingency conditions. The Program Executive Officer, Fleet Hospital Program is responsible for ensuring planning, programming and budgeting; design, redesign and

procurement; and integrated logistics support for the Fleet Hospital deployable platforms. The Commanding Officer is responsible for the organization and management of all resources of NAVMEDLOGCOM in accomplishing the assigned mission. The Commanding Officer exercises military jurisdiction over the command. Duties and responsibilities are outlined in Navy regulations and the Manual of the Medical Department. The Commanding Officer may delegate duties to the Executive Officer and other subordinates; however, such delegation of authority in no way relieves the Commanding Officer of responsibility.

### **EXECUTIVE OFFICER (Code 09)**

Serves as Executive Officer and assumes command in the absence of the Commanding Officer. The Executive Officer is the direct representative of the Commanding Officer in coordinating the administration of the command. All orders issued by the Executive Officer are regarded as emanating from the Commanding Officer and shall govern all persons within the command. The Executive Officer is responsible to the Commanding Officer for accomplishing the command mission efficiently per applicable rules, regulations and instructions. The Executive Officer will conform to and implement the policies and orders of the Commanding Officer and keep the Commanding Officer informed of all significant matters pertaining to the Command. In the absence of the incumbent, the acting Executive Officer will have the same authority and responsibility as the Executive Officer but will initiate no procedural changes unless otherwise directed.

### **SPECIAL ASSISTANTS**

Special Assistants to the Commanding Officer serve as directed and have direct access to the Commanding Officer in the performance of their duty as special assistants. Special Assistants include: Program Manager Fleet Hospital Program, PML-500 (Code 00A); Management Control Officer and Lead ISO Auditor (Code 00B); Command Senior Chief (Code 00C); Safety Manager (Code 00D); Competition Advocate (Code 00F); Counsel (Code 00L); Small & Disadvantaged Business Utilization Specialist (Code 00M); Civilian Personnel Liaison (Code 00P); Total Quality Leadership Coordinator (Code 00Q); Command Managed Equal Opportunity Officer (Code 00R); Comptroller (Code 00S); and ISO Management Representative (Code 00T).

### **ADMINISTRATION DIRECTORATE (Code 01)**

The Director, Administration is responsible for the management of the personnel, administrative, resource management, training and IM/IT programs for the command.

### **ACQUISITION MANAGEMENT DIRECTORATE (Code 02)**

The Director, Acquisition Management is responsible for coordinating health care services contracting policy and procedures within the BUMED claimancy and is responsible for procurement of equipment, supplies and services in support of the Operating Forces, FMF and Navy MTFs and DTFs.

**EQUIPMENT SUPPORT DIRECTORATE (Code 03)**

The Director, Equipment Support is responsible for coordinating with other BUMED principals, claimancy commands, and systems commands to ensure that appropriate and timely medical equipment and logistic planning is accomplished to fulfill new or changing requirements in support of projected peacetime and wartime missions, tasks, and functions. Coordinates the materiel and logistic efforts of BUMED claimancy activities by providing guidance, logistic support, technical appraisals of requirements and procedures, and recommended courses of actions. Ensures technical support and management of equipment programs having Navy-wide applications. Responsible for development and management of medical and dental equipment specifications, repair parts provisioning and maintenance systems for fleet and shore facilities. Provide biomedical engineering technical support and assistance for all equipment.

**NAVAL EXPEDITIONARY MEDICAL SUPPORT SYSTEMS DIRECTORATE (Code 04)**

The Director, Naval Expeditionary Medical Support Systems (NEMSS) is responsible for management of BUMED/CINC directed contingency programs and provides medical and dental logistics support to the operating forces.

**FORCE HEALTH SUPPORT DIRECTORATE (Code 06)**

The Director, Force Health Support is responsible as the command's focal point for customer issues, concerns, questions and inquiries. Furthermore, the Director is responsible for coordinating the marketing of the command mission, functions, operations and initiatives. The Director is also responsible as the Navy service representative in all matters that pertain to the various Medical Prime Vendor Programs and Immunization Programs.

**HEALTHCARE SERVICES SUPPORT DIRECTORATE (Code 07)**

The Director, Healthcare Services Support is responsible for the development, implementation and evaluation of health service acquisition strategies for BUMED, DOD, and other customers.

**BUSINESS SYSTEMS SUPPORT DIRECTORATE (Code08)**

The Director, Business Systems Support is responsible for coordinating, communicating and representing the Navy Medical Department's logistics input, position and policy pertaining to the Defense Medical Logistics Standard Support System (DMLSS). Acts as Navy Medical Department's logistics representative in all matters pertaining to the integration of all DMLSS-Retail modules into Military Treatment Facilities, and functionally pertinent DMLSS modules into Fleet and Fleet Marine Force Automated Information Systems (AIS). Serves as Naval Medical Logistics Command's technical information source for all Department of Defense (DoD) AIS with logistics applications. Works closely with Code 03 to integrate state of the art IM/IT into medical equipment procurements.

**NAVMEDLOGCOM DET PIRMASENS**

The Officer-in-Charge provides naval medical logistics assistance to the United States Army Medical Materiel Center Europe as necessary and serves as the NAVMEDLOGCOM representative for all shore commands and operating forces in the European Theater.

## Appendix B - Command Quality Management System Key Personnel Duties and Qualifications

**MANAGEMENT REPRESENTATIVE** - Responsible for and has the defined authority to:

- a. Establish, implement, and maintain NMLC's Quality Management System in accordance with ANSI/ASQC Q9002-1994, the American National Standard; Quality Systems – Model for Quality Assurance in Production, Installation, and Servicing.
- b. The Management Representative must:
  - (1) Be knowledgeable about traditional quality assurance and quality control technologies.
  - (2) Have an understanding of the series of standards and the strategic role ISO 9000 plays in the Command.
  - (3) Have a commitment to the importance of ISO 9000.
  - (4) Be an authority figure, ideally with seniority and experience that cuts across departmental lines.
  - (5) Have superior communication skills.
  - (6) Carry the backing of the Commanding Officer.
- c. The Management Representative must be a Lieutenant Commander, Medical Service Corps Officer or higher and have successfully completed an Internal Auditing Course. It is highly recommended that the candidate have 18 months remaining onboard upon appointment.

**COMMAND INTERNAL AUDIT OFFICER** - Responsible for and has the defined authority to:

- a. Establish and maintain documented procedures for planning and implementing internal quality audits and to determine the effectiveness of the Quality Management System (QMS).
- b. Develop an annual audit schedule based on the status and importance of the activity to be audited ensuring initial and follow-up audits are scheduled and carried out by personnel independent of those having direct responsibility for the activity being audited.
- c. Assign auditors and ensure auditors are qualified and remain qualified.
- d. Ensure the results of audits are recorded and brought to the attention of the process owners for timely corrective and preventive action.
- e. And provide the ESC with an Internal Auditing System Summary not less than quarterly and assist the Management Representative in reporting the performance of the QMS to the ESC for management review and as a basis for continuous quality improvement.

The Command Internal Audit Officer must be a Lieutenant, Medical Service Corps Officer or higher and have successfully completed a Lead Internal Auditors Course. It is highly recommended that the candidate have 18 months remaining onboard upon appointment.

**CORRECTIVE ACTION COORDINATOR** - Responsible for and has the defined authority to:

- a. Assist the Corrective Action Administrator, who is the Command Executive Officer by position, in establishing and maintaining documented procedures for implementing corrective and preventive action and managing the overall Corrective and Preventive Action Program.
- b. Establish and maintain the corrective action electronic log and database for tracking individual Corrective and Preventive Action Requests/Reports (CARs).
- c. Assign CAR numbers and route CARS, upon approval, to the appropriate process owner.
- d. Establish and maintain a CAR tickler system to ensure outstanding CARs are appropriately identified and monitored through closure.
- e. Assist the Command Internal Audit Officer with the Command Internal Audit Program.

The Corrective Action Coordinator must be a Lieutenant, Medical Service Corps Officer, Civilian GS-11, or higher and have successfully completed an Internal Audit Course. It is highly recommended that the candidate have 18 months remaining onboard upon appointment.

**QUALITY DOCUMENT CONTROL COORDINATOR** – Responsible for and has the defined authority to:

- a. Establish and maintain documented procedures to control all documents and data that relate to NMLC's QMS including, to the extent applicable, documents of external origin.
- b. Adequately provide for a means of approval, issue, distribution, control, and revision of documents and ensure each document has been reviewed for adequacy and is in the proper format to use.
- c. Maintain a master list or "ISO Quality Map" of all documents in the QMS and the revision status of each that matches exactly with controlled hard copies and the controlled documents on the NMLC Intranet.
- d. Work closely with the Command Quality Records Coordinator to ensure that Quality Records information is collected and the Quality Records Matrix is updated as documents are released or revised.

The Quality Document Control Coordinator must be a First Class Petty Officer, Civilian GS-7 or equivalent level contractor or higher. The candidate must have excellent computer and communication skills. It is highly recommended that the candidate have 18 months remaining onboard upon appointment.

**QUALITY RECORDS COORDINATOR** – Responsible for and has the defined authority to:

- a. Establish and maintain documented procedures for the identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.
- b. Establish and maintain a Master List of all quality records identifying quality record name, storage location, indexing method, retention period, associated process number, quality record identification number, disposition instructions, and whether the record is in-scope or not.
- c. Work closely with the Command Document Control Coordinator to ensure that Quality Records information is collected and the Quality Records Matrix is updated as documents are released or revised.

The Quality Records Coordinator must be a First Class Petty Officer, Civilian GS-7 or equivalent level contractor or higher. The candidate must have excellent computer and communication skills. It is highly recommended that the candidate have 18 months remaining onboard upon appointment.

## Change Record

Rev	Date	Responsible Person	Description of Change
B	6 July 99	Management Representative	Administrative changes and changes for clarification based on CARs as a result of Internal Audits
C	16 Aug 99	Management Representative	Addition of Appendix B, administrative changes and changes for clarification as a result of the Pre-Assessment.
D	23 Nov 99	Management Representative	Sections 4.2 Quality Planning and 4.12 Inspection and Test Status rewritten to address SGS recommendation and CAR respectively.
E	13 Apr 00	Management Representative	Changes made to reflect new command organization
F	30 Nov 00	Management Representative	Changes to NMLC Strategic Goals & Objectives; changes to Corrective Action Procedures; added definition of "customer" in 4.13